

111TH CONGRESS  
1ST SESSION

# H. R. 2400

To amend the Public Health Service Act to enhance efforts to address  
antimicrobial resistance.

---

## IN THE HOUSE OF REPRESENTATIVES

MAY 13, 2009

Mr. MATHESON introduced the following bill; which was referred to the  
Committee on Energy and Commerce

---

## A BILL

To amend the Public Health Service Act to enhance efforts  
to address antimicrobial resistance.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Strategies to Address  
5       Antimicrobial Resistance Act”.

6       **SEC. 2. FINDINGS.**

7       The Congress finds as follows:

8               (1) The advent of the antibiotic era has saved  
9       millions of lives and allowed for incredible medical  
10      progress; however, the increased use and overuse of

1 antimicrobial drugs have correlated with increased  
2 rates of antimicrobial resistance.

3 (2) Through mutation as well as other mecha-  
4 nisms, bacteria and other infectious disease-causing  
5 organisms—viruses, fungi, and parasites—develop  
6 resistance to antimicrobial drugs over time. The  
7 more antimicrobial drugs are used, whether appro-  
8 priately or inappropriately, the more this contributes  
9 to the development of antimicrobial resistance.

10 (3) The recent 2009 Influenza A: H1N1 virus  
11 (also known as “Swine Flu Virus”) outbreak clearly  
12 illustrates why infectious diseases experts are con-  
13 cerned about drug resistance; although the H1N1  
14 virus currently appears to be treatable by two class-  
15 es of available antiviral drugs, it is resistant to other  
16 classes, and should the virus mutate and become re-  
17 sistant to all classes, which is possible, we would be  
18 left extremely vulnerable.

19 (4) Scientific evidence suggests that the devel-  
20 opment of antimicrobial resistance in humans is not  
21 due only to use of antimicrobial drugs in humans,  
22 but also may be caused by the use of antimicrobial  
23 drugs in food-producing animals.

24 (5) A study estimates that in 2005 more than  
25 94,000 invasive methicillin-resistant *Staphylococcus*

1 aureus (MRSA) infections occurred in the United  
2 States and more than 18,500 of these infections re-  
3 sulted in death—7 times more than a decade earlier.

4 (6) The recent 2009 Influenza A: H1N1 virus  
5 outbreak exacerbates concerns about MRSA and  
6 other bacteria that cause respiratory diseases given  
7 that, during the 1918 influenza pandemic, many  
8 thousands of deaths were caused by complications  
9 due to secondary bacterial infections and not by the  
10 influenza virus itself.

11 (7) Each year, nearly 2,000,000 people contract  
12 bacterial infections in hospitals and approximately  
13 90,000 of these people die from these infections.

14 (8) The current annual costs of antimicrobial-  
15 resistant bacterial diseases are hard to quantify, but  
16 a 1995 report by the Office of Technology Assess-  
17 ment, an agency of Congress, which looked at 6 dif-  
18 ferent antimicrobial-resistant strains of bacteria, cal-  
19 culated that the minimum nationwide hospital costs  
20 of just these strains of bacteria accounted for  
21 \$1,300,000,000 annually in 1992 dollars  
22 (\$1,870,000,000 in 2006 dollars).

23 (9) A 1998 Institute of Medicine report esti-  
24 mated the societal cost of resistance as between  
25 \$4,000,000,000 to \$5,000,000,000; many experts

1       argue the cost in 2009 may be close to 10 times  
2       greater.

3               (10) The costs of antimicrobial-resistant infec-  
4       tions in terms of lives lost and economically will only  
5       rise as antimicrobial resistance continues to spread.

6   **SEC. 3. ANTIMICROBIAL RESISTANCE TASK FORCE.**

7       (a) IN GENERAL.—Section 319E of the Public  
8   Health Service Act (42 U.S.C. 247d–5) is amended—

9               (1) in subsection (a)—

10               (A) in the subsection heading, by striking  
11       “TASK FORCE” and inserting the following:  
12       “ANTIMICROBIAL RESISTANCE OFFICE, TASK  
13       FORCE, AND ADVISORY BOARD”;

14               (B) in paragraph (1)—

15               (i) by striking “as of the date of the  
16       enactment of this section” and inserting  
17       “as of September 30, 2006”; and

18               (ii) by adding at the end the fol-  
19       lowing: “The Secretary shall, not later  
20       than 1 year after the date of enactment of  
21       the Strategies to Address Antimicrobial  
22       Resistance Act, establish an Antimicrobial  
23       Resistance Office in the Office of the Sec-  
24       retary and appoint a director to that Of-  
25       fice. The Secretary shall, not later than 1

1 year after the date of enactment of such  
2 Act, establish the Public Health Anti-  
3 microbial Advisory Board as an advisory  
4 board to the Director of the Antimicrobial  
5 Resistance Office. The Director of the  
6 Antimicrobial Resistance Office shall serve  
7 as the Director of the task force. To avoid  
8 duplication and ensure that Federal re-  
9 sources are used efficiently and effectively,  
10 the Director shall work in conjunction with  
11 the Federal agencies represented on the  
12 Task Force to coordinate all antimicrobial  
13 resistance activities undertaken and sup-  
14 ported by the Federal Government, includ-  
15 ing the activities and budgetary allocations  
16 of the Office, task force, and Public Health  
17 Antimicrobial Advisory Board.”;

18 (C) by amending paragraph (2) to read as  
19 follows:

20 “(2) MEMBERS.—

21 “(A) MEMBERS OF THE ANTIMICROBIAL  
22 RESISTANCE TASK FORCE.—The task force de-  
23 scribed in paragraph (1) shall be composed of  
24 representatives of such Federal agencies as the

1 Secretary determines necessary, including rep-  
2 resentation of the following:

3 “(i) The Antimicrobial Resistance Of-  
4 fice.

5 “(ii) The Assistant Secretary of Pre-  
6 paredness and Response.

7 “(iii) The Centers for Disease Control  
8 and Prevention.

9 “(iv) The Food and Drug Administra-  
10 tion.

11 “(v) The National Institutes of  
12 Health.

13 “(vi) The Agency for Healthcare Re-  
14 search and Quality.

15 “(vii) The Centers for Medicare &  
16 Medicaid Services.

17 “(viii) The Health Resources and  
18 Services Administration.

19 “(ix) The Department of Agriculture.

20 “(x) The Department of Education.

21 “(xi) The Department of Defense.

22 “(xii) The Department of Veterans  
23 Affairs.

24 “(xiii) The Environmental Protection  
25 Agency.

1 “(xiv) The Department of Homeland  
2 Security.

3 “(xv) The United States Agency for  
4 International Development.

5 “(B) MEMBERS OF THE PUBLIC HEALTH  
6 ANTIMICROBIAL ADVISORY BOARD.—

7 “(i) IN GENERAL.—The Public Health  
8 Antimicrobial Advisory Board shall be  
9 composed of 19 voting members, appointed  
10 by the Secretary. Such members shall in-  
11 clude experts from the medical professions  
12 (including hospital and community-based  
13 physicians), pharmacy, public health, vet-  
14 erinary, research, and international health  
15 communities, as well as one representative  
16 from a public interest group.

17 “(ii) TERMS.—Each member ap-  
18 pointed under clause (i) shall be appointed  
19 for a term of 3 years, except that of the  
20 19 members first appointed—

21 “(I) 6 shall be appointed for a  
22 term of 12 months; and

23 “(II) 6 shall be appointed for a  
24 term of 2 years.

1 “(iii) CHAIR.—The Secretary shall ap-  
 2 point a Chair of the Public Health Anti-  
 3 microbial Advisory Board from among its  
 4 members to lead and supervise the activi-  
 5 ties of the Advisory Board.

6 “(iv) DISCLOSURE OF FINANCIAL IN-  
 7 TERESTS.—Prior to a meeting of the Pub-  
 8 lic Health Antimicrobial Advisory Board,  
 9 each member of the Advisory Board shall  
 10 disclose to the Secretary any potential, rel-  
 11 evant financial interests as defined under  
 12 section 208(a) of title 18, United States  
 13 Code.”;

14 (D) in paragraph (3)(B), by striking “in  
 15 consultation with the task force described in  
 16 paragraph (1) and” and inserting “acting  
 17 through the Director of the Antimicrobial Re-  
 18 sistance Office and the Director of the Centers  
 19 for Disease Control and Prevention, and in con-  
 20 sultation with”; and

21 (E) by amending paragraph (4) to read as  
 22 follows:

23 “(4) MEETINGS AND DUTIES.—

24 “(A) ANTIMICROBIAL RESISTANCE OFFICE  
 25 RESISTANCE DUTIES.—The Director of the



1 Antimicrobial Resistance Office, working in  
2 conjunction with the Federal agencies that are  
3 represented on the task force described in para-  
4 graph (1), shall issue an update to the Public  
5 Health Action Plan to Combat Antimicrobial  
6 Resistance within 18 months of the establish-  
7 ment of the Office and biennial updates there-  
8 after. The updates shall include enhanced plans  
9 for addressing antimicrobial resistance in the  
10 United States and internationally. The Director  
11 of the Office shall post on a website these up-  
12 dates as well as summaries of all non-propri-  
13 etary data the Task Force makes available. The  
14 Director of the Antimicrobial Resistance Office  
15 shall work in conjunction with the Federal  
16 agencies that are represented on the task force  
17 described in paragraph (1), and in consultation  
18 with the Public Health Antimicrobial Advisory  
19 Board, to—

20 “(i) establish benchmarks for achiev-  
21 ing the goals set forth in the action plan;

22 “(ii) assess the ongoing, observed pat-  
23 terns of emergence of antimicrobial resist-  
24 ance, and their impact on clinical outcomes

1 in terms of how patients feel, function, or  
2 survive;

3 “(iii) assess how antimicrobial prod-  
4 ucts are being used in humans, animals,  
5 and plants, and the impact of such use in  
6 furthering the development of resistance  
7 and the implications thereof for patient  
8 safety and public health;

9 “(iv) establish a priority list of human  
10 infectious diseases with the greatest need  
11 for development of new point-of-care and  
12 other diagnostics, antimicrobial drugs, and  
13 vaccines, and in particular serious and life-  
14 threatening bacterial diseases, for which  
15 there are few or no diagnostic or treatment  
16 options;

17 “(v) recommend basic, clinical, epide-  
18 miological, prevention, and translational  
19 research where additional federally sup-  
20 ported studies may be beneficial;

21 “(vi) recommend how to support anti-  
22 microbial development through Food and  
23 Drug Administration activities, including  
24 through the agency’s Critical Path Initia-  
25 tive;

1 “(vii) recommend how best to  
2 strengthen and link antimicrobial resist-  
3 ance-related surveillance and prevention  
4 and control activities; and

5 “(viii) collaborate with the Assistant  
6 Secretary for Preparedness and Response  
7 to ensure that strategies to address anti-  
8 microbial-resistance are coordinated with  
9 initiatives aimed at pandemic influenza, in-  
10 cluding the 2009 Influenza A: H1N1 virus  
11 and H1N1 Avian Influenza virus, severe  
12 acute respiratory syndrome, bioterrorism,  
13 and other emerging health threats.

14 “(B) ANTIMICROBIAL RESISTANCE TASK  
15 FORCE MEETINGS AND DUTIES.—

16 “(i) MEETINGS.—The Antimicrobial  
17 Resistance Task Force shall convene peri-  
18 odically as the Director of the Anti-  
19 microbial Resistance Task Force deter-  
20 mines to be appropriate, but not fewer  
21 than twice a year, to consider issues relat-  
22 ing to antimicrobial resistance.

23 “(ii) PUBLIC HEALTH ACTION  
24 PLAN.—At least twice a year, the task  
25 force described in paragraph (1) shall have

1 a meeting to review, discuss, and further  
2 develop the Public Health Action Plan to  
3 Combat Antimicrobial Resistance issued by  
4 the interagency task force on antimicrobial  
5 resistance in 2001. Among other issues,  
6 the task force may discuss and review,  
7 based on current need or concern—

8 “(I) antimicrobial clinical suscep-  
9 tibility concentrations proposed, estab-  
10 lished, or updated by the Food and  
11 Drug Administration;

12 “(II) data obtained by govern-  
13 ment agencies and, as possible, by pri-  
14 vate sources on emerging anti-  
15 microbial resistance related to clinical  
16 outcomes in terms of how patients  
17 function, feel, or survive as well as  
18 data related to how antimicrobial  
19 drugs may have been used inappropri-  
20 ately;

21 “(III) surveillance data and pre-  
22 vention and control activities regard-  
23 ing emerging antimicrobial resistance  
24 from reliable sources including the  
25 Centers for Disease Control and Pre-

1           vention, the Food and Drug Adminis-  
2           tration, the Department of Defense,  
3           the Department of Veterans Affairs,  
4           the Department of Agriculture, the  
5           Environmental Protection Agency,  
6           and as feasible from private sources  
7           and international bodies;

8                   “(IV) data on the amount of  
9           antimicrobial products used in hu-  
10          mans, animals, and plants from reli-  
11          able sources including data from the  
12          Centers for Disease Control and Pre-  
13          vention, the Food and Drug Adminis-  
14          tration, the Environmental Protection  
15          Agency, the Department of Veterans  
16          Affairs, the Centers for Medicare &  
17          Medicaid Services, the Department of  
18          Homeland Security, and the Depart-  
19          ment of Agriculture, and as feasible  
20          from private sources and international  
21          bodies;

22                   “(V) the impact of antimicrobial  
23          resistance on human health resulting  
24          from the approval of antimicrobial  
25          drugs for use in humans or animals

1 (including consideration of and rec-  
2 ommendations on potential manage-  
3 ment plans to limit and reduce the  
4 negative impacts of such resistance on  
5 human health);

6 “(VI) reports of federally sup-  
7 ported antimicrobial resistance re-  
8 search and antimicrobial drug devel-  
9 opment research activities (including  
10 clinical, epidemiological, prevention,  
11 and translational research) obtained  
12 from Federal agencies, as well as re-  
13 ports of research sponsored by other  
14 countries, industry, and non-govern-  
15 mental organizations;

16 “(VII) reports on efforts by the  
17 Food and Drug Administration to de-  
18 velop policies and guidances which en-  
19 courage antimicrobial drug develop-  
20 ment and appropriate use while main-  
21 taining high standards for safety and  
22 effectiveness;

23 “(VIII) health plan employer  
24 data and information set (HEDIS)

1 measures pertaining to appropriate  
2 use of antimicrobial drugs; and

3 “(IX) other data and issues the  
4 task force described in paragraph (1)  
5 identifies as relevant to the issue of  
6 antimicrobial resistance.

7 “(iii) PENDING APPLICATIONS.—The  
8 Food and Drug Administration may con-  
9 sult with the Director of the Antimicrobial  
10 Resistance Office concerning the pending  
11 application of any antimicrobial drug appli-  
12 cation submitted to the Secretary under  
13 section 505 or 512 of the Federal Food,  
14 Drug, and Cosmetic Act or the Public  
15 Health Service Act.

16 “(C) PUBLIC HEALTH ANTIMICROBIAL AD-  
17 VISORY BOARD MEETINGS AND DUTIES.—

18 “(i) MEETINGS.—The Public Health  
19 Antimicrobial Advisory Board shall meet  
20 as the Chair of the Public Health Anti-  
21 microbial Advisory Board determines to be  
22 appropriate, preferably in conjunction with  
23 meetings of the Antimicrobial Resistance  
24 Task Force, but not fewer than 2 times  
25 each year.

1           “(ii) RECOMMENDATIONS.—The Pub-  
2           lic Health Antimicrobial Advisory Board  
3           shall make recommendations to the Sec-  
4           retary, and the Antimicrobial Resistance  
5           Office, regarding—

6                   “(I) ways to encourage the avail-  
7                   ability of an adequate supply of safe  
8                   and effective antimicrobial products;

9                   “(II) research priorities and  
10                  other measures (such as antimicrobial  
11                  drug resistance management plans) to  
12                  enhance the safety and efficacy of  
13                  antimicrobial products;

14                  “(III) how best to implement and  
15                  update the goals of the Public Health  
16                  Action Plan to Combat Antimicrobial  
17                  Resistance;

18                  “(IV) incentives necessary to es-  
19                  tablish uniform mechanisms and data  
20                  sets for State and local reporting of  
21                  resistance data;

22                  “(V) the adequacy of existing  
23                  surveillance systems to collect anti-  
24                  microbial resistance data and how



1 best to improve the collection, report-  
2 ing, and analysis of such data;

3 “(VI) the development of a na-  
4 tional plan for the collection and anal-  
5 ysis of isolates of resistant pathogens,  
6 including establishing priorities as to  
7 which isolates should be collected;

8 “(VII) the implementation and  
9 evaluation of interventions to promote  
10 appropriate antimicrobial drug use in  
11 both inpatient and outpatient settings;  
12 and

13 “(VIII) areas for government,  
14 nongovernment, and international co-  
15 operation to strengthen implementa-  
16 tion of the Public Health Action Plan  
17 to Combat Antimicrobial Resistance.

18 “(D) AVAILABILITY OF INFORMATION.—  
19 The Antimicrobial Resistance Office shall en-  
20 sure that all information shall be made avail-  
21 able to the public on the website described in  
22 subparagraph (A) consistent with section 8 of  
23 the Strategies to Address Antimicrobial Resist-  
24 ance Act.”;

1           (2) by amending subsection (b) to read as fol-  
2       lows:

3       “(b) ANTIMICROBIAL RESISTANCE STRATEGIC RE-  
4       SEARCH PLAN.—The Secretary, acting through the Direc-  
5       tor of the Antimicrobial Resistance Office, the Director  
6       of the Centers for Disease Control and Prevention, and  
7       the Director of the National Institutes of Health, and in  
8       consultation with other Federal agencies and the Public  
9       Health Antimicrobial Advisory Board, shall develop an  
10      antimicrobial resistance strategic research plan that  
11      strengthens existing epidemiological, interventional, clin-  
12      ical, behavioral, translational, and basic research efforts  
13      to advance the understanding of—

14           “(1) the development, implementation, and effi-  
15      cacy of interventions to prevent and control the  
16      emergence and transmission of antimicrobial resist-  
17      ance;

18           “(2) how best to optimize antimicrobial effec-  
19      tiveness while limiting the emergence of resistance,  
20      including addressing issues related to duration of  
21      therapy, effectiveness of therapy in self-resolving dis-  
22      eases, and determining populations most likely to  
23      benefit from antimicrobial drugs;

24           “(3) the extent to which the use of anti-  
25      microbial products in humans, animals, plants, and

1 other uses accelerates development and transmission  
2 of antimicrobial resistance;

3 “(4) the natural histories of infectious diseases  
4 (including defining the disease, diagnosis, severity,  
5 and the time course of illness);

6 “(5) the development of new therapeutics, in-  
7 cluding antimicrobial drugs, biologics, and devices  
8 against resistant pathogens, and in particular dis-  
9 eases for which few or no therapeutics are in devel-  
10 opment;

11 “(6) the development and testing of medical  
12 diagnostics to identify patients with infectious dis-  
13 ease and identify the exact cause of infectious dis-  
14 eases syndromes, particularly with respect to the de-  
15 tection of pathogens resistant to antimicrobial drugs;

16 “(7) the epidemiology, pathogenesis, mecha-  
17 nisms, and genetics of antimicrobial resistance; and

18 “(8) the sequencing of the genomes, or other  
19 DNA analysis, or other comparative analysis of pri-  
20 ority pathogens (as determined by the Public Health  
21 Antimicrobial Advisory Board), in collaboration with  
22 the Department of Defense and the Joint Genome  
23 Institute of the Department of Energy.”;

24 (3) in subsection (c)—

1 (A) by inserting “acting through the Di-  
2 rector of the Antimicrobial Resistance Office,”  
3 after “The Secretary,”; and

4 (B) by striking “members of the task force  
5 described in subsection (a),”;

6 (4) in subsection (d)(1), by inserting “, through  
7 the Antimicrobial Resistance Office,” after “The  
8 Secretary”; and

9 (5) in subsection (e)—

10 (A) in paragraph (1), by inserting “, act-  
11 ing through the Director of the Antimicrobial  
12 Resistance Office,” after “The Secretary”;

13 (B) in paragraph (3), by inserting “, act-  
14 ing through the Antimicrobial Resistance Of-  
15 fice,” after “The Secretary”; and

16 (C) by adding at the end the following:

17 “(4) PREFERENCE IN MAKING AWARDS.—In  
18 making awards under paragraph (1), the Secretary  
19 shall give preference to eligible entities that will use  
20 grant funds to establish demonstration projects to  
21 assess the scope of the antimicrobial resistance prob-  
22 lem and the level of appropriate and inappropriate  
23 use of antimicrobial drugs especially related to self-  
24 resolving infections, including the validation of mod-  
25 els that may lead to the development of quality

1 measures for health care providers prescribing anti-  
2 microbial drugs.”.

3 (b) ENSURE ACCESS TO ANTIMICROBIAL DATA AND  
4 RESEARCH.—The Director of the Antimicrobial Resist-  
5 ance Office shall work with the agencies represented on  
6 the Antimicrobial Resistance Task Force to identify rel-  
7 evant data and formats, and mechanisms for commu-  
8 nicating such data to the Antimicrobial Resistance Office  
9 and Antimicrobial Resistance Task Force and, in a man-  
10 ner consistent with section 8 of this Act, with the Public  
11 Health Antimicrobial Advisory Board and the public, in-  
12 cluding relevant data obtained by the agencies through  
13 contracts with other organizations, including—

14 (1) use and clinical outcomes data on patients  
15 receiving antimicrobial drugs for the treatment, pre-  
16 vention, or diagnosis of infection or infectious dis-  
17 eases;

18 (2) surveillance data regarding emerging anti-  
19 microbial drug resistance;

20 (3) susceptibility data related to antimicrobial  
21 drug use;

22 (4) data related to the amount of antimicrobial  
23 products used in humans, animals, and plants;

24 (5) data from federally funded research in-  
25 tended to support antimicrobial drug development;

1           (6) data demonstrating the impact of research,  
2           surveillance, and prevention and control initiatives in  
3           understanding and controlling antimicrobial resist-  
4           ance; and

5           (7) data regarding implementation and evalua-  
6           tion of interventions to improve antimicrobial drug  
7           prescribing practices.

8   **SEC. 4. COLLECTION OF ANTIMICROBIAL DRUG DATA.**

9           (a) SUBMISSION OF HUMAN AND ANIMAL DRUG DIS-  
10   TRIBUTION DATA.—Chapter V of the Federal Food, Drug,  
11   and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by  
12   inserting after section 512 the following:

13   **“SEC. 512A. SUBMISSION OF HUMAN AND ANIMAL DRUG**  
14                   **DISTRIBUTION DATA.**

15           “(a) IN GENERAL.—Notwithstanding any other pro-  
16   vision of law, the Secretary shall require that each sponsor  
17   of a human antimicrobial drug product which is approved  
18   under section 505 (including section 505(j)) and sold or  
19   distributed in the United States, submit antimicrobial  
20   drug sales and distribution data. Such data shall be—

21           “(1) submitted not later than 60 days after the  
22           beginning of the subsequent calendar year;

23           “(2) reported on the calendar year and seg-  
24           regated by month;

1 “(3) in such format, and utilize any such unit  
 2 of measure, as the Secretary by regulation deems  
 3 necessary and appropriate to ensure the reported  
 4 data is comparable and reliable; and

5 “(4) made available to the Antimicrobial Resist-  
 6 ance Office and the Antimicrobial Resistance Task  
 7 Force.

8 “(b) CONFIDENTIALITY.—To protect proprietary  
 9 commercial information, officials who serve in the Anti-  
 10 microbial Resistance Office and on the Antimicrobial Re-  
 11 sistance Task Force shall sign a confidentiality agreement  
 12 prior to reviewing any such data to which access is granted  
 13 under subsection (a)(4).”.

14 (b) SUBMISSION OF ANIMAL SALES AND DISTRIBUTION DATA.—Section 512(l)(3) (21 U.S.C. 360b(l)(3)) is  
 15 amended—  
 16 amended—

17 (1) in subparagraph (C)—

18 (A) in clause (ii), by deleting “and” at the  
 19 end;

20 (B) in clause (iii), by striking the period at  
 21 the end and inserting “; and”; and

22 (C) by adding at the end the following:

23 “(iv) contain any such additional in-  
 24 formation, be in such format, and utilize  
 25 any such unit of measure as the Secretary

1 by regulation deems necessary and appro-  
2 priate to ensure the reported data is com-  
3 parable and reliable.”; and

4 (2) in subparagraph (D), by striking “may”  
5 and inserting “shall”.

6 (c) DATA FROM ADDITIONAL SOURCES.—

7 (1) IN GENERAL.—The Secretary, acting  
8 through the Director of the Antimicrobial Resistance  
9 Office, shall explore opportunities to secure from pri-  
10 vate vendors and health care organizations reliable  
11 and comparable animal and human antimicrobial  
12 drug consumption data (volume antimicrobial dis-  
13 tribution data and antimicrobial use, including pre-  
14 scription data) by State or metropolitan area, as  
15 necessary, to supplement the antimicrobial drug con-  
16 sumption data to be collected under this section for  
17 the purpose of demonstrating how the consumption  
18 of antimicrobial drugs for human and animal uses  
19 may affect the development of resistance over time  
20 and within geographic locations and to institute pre-  
21 ventive interventions.

22 (2) NEGOTIATIONS.—The Director of the Anti-  
23 microbial Resistance Office may enter into negotia-  
24 tions with private vendors and health care organiza-  
25 tions to determine acceptable scope and parameters



1 for summaries of antimicrobial drug consumption  
2 data that is collected under this section publicly  
3 available for research purposes.

4 (3) OTHER MEANS TO SECURE DATA.—If the  
5 Director of the Antimicrobial Resistance Office is  
6 not able to secure sufficient supplemental anti-  
7 microbial drug consumption data for human and  
8 animal uses through private vendors and health care  
9 organizations as provided for in this section, the  
10 Secretary shall consider other means to secure such  
11 consumption data, including through the conduct of  
12 surveys about how antimicrobial drugs are used in  
13 various settings.

14 (d) COLLECTION OF ANTIMICROBIAL PRESCRIPTION  
15 DATA.—

16 (1) CLINICAL OUTCOMES DATA.—The Director  
17 of the Antimicrobial Resistance Office, the Under  
18 Secretary for Health of the Department of Veterans  
19 Affairs, and the Administrator of the Centers for  
20 Medicare & Medicaid Services shall work together to  
21 collect and analyze relevant drug utilization data  
22 and clinical outcomes data, as determined relevant  
23 by the Director of the Antimicrobial Resistance Of-  
24 fice, on patients who receive services funded by such  
25 agencies and who are receiving prescription anti-

1 microbial agents for the treatment or prevention of  
2 infection or infectious diseases.

3 (2) ORGANIZATION.—Any data collected under  
4 paragraph (1) shall be organized by—

5 (A) indication (including results of diag-  
6 nostic studies when available);

7 (B) dosage;

8 (C) route of administration;

9 (D) duration;

10 (E) age of the patient; and

11 (F) geographic region.

12 (3) INTERVENTIONS AND ANALYSIS.—The  
13 Under Secretary for Health of the Department of  
14 Veterans Affairs, the Administrator of the Centers  
15 for Medicare & Medicaid Services, and the Director  
16 of the Antimicrobial Resistance Office shall work to-  
17 gether to identify and report upon interventions that  
18 prevent and control the development of antimicrobial  
19 resistance and to include within such reports, where  
20 appropriate, an analysis of the following—

21 (A) intra- and extra-label antimicrobial  
22 use;

23 (B) where challenges to appropriate use re-  
24 main;

1 (C) trends and variations in antimicrobial  
2 resistance rates; and

3 (D) the relationship between drug use and  
4 resistance.

5 (e) PUBLIC AVAILABILITY OF DATA.—The Director  
6 of the Antimicrobial Resistance Office shall make sum-  
7 maries of the data received under this section publicly  
8 available and ensure that such summaries are updated and  
9 published, in a manner consistent with section 8, at least  
10 once annually on the website described in section  
11 319E(a)(4)(A) of the Public Health Service Act (42  
12 U.S.C. 247d–5(a)(4)(A)) in order to support epidemiologic  
13 and microbiologic research.

14 **SEC. 5. ANTIMICROBIAL RESISTANCE SURVEILLANCE AND**  
15 **RESEARCH NETWORK.**

16 (a) IN GENERAL.—The Secretary, through the Direc-  
17 tor of the Centers for Disease Control and Prevention and  
18 the Director of the National Institutes of Health, shall es-  
19 tablish at least 10 Antimicrobial Resistance Surveillance  
20 and Research Network sites to strengthen the national ca-  
21 pacity to—

22 (1) describe and confirm regional outbreaks  
23 through surveillance of locally available clinical  
24 specimens;

1           (2) assess, integrate, and address local and na-  
2           tional antimicrobial resistance patterns;

3           (3) facilitate research on prevention, control,  
4           and treatment of resistant organisms; and

5           (4) serve as a clinical trials network for opti-  
6           mizing antimicrobial drug effectiveness.

7           (b) GEOGRAPHIC DISTRIBUTION.—The sites estab-  
8           lished under subsection (a) shall be geographically distrib-  
9           uted across the United States.

10          (c) NONDUPLICATION OF CURRENT NATIONAL CA-  
11          PACITY.—The sites established under subsection (a) may  
12          be based in academic centers, health departments, and ex-  
13          isting surveillance sites.

14          (d) RESPONSIBILITIES.—The Network of sites estab-  
15          lished under subsection (a) shall—

16               (1) monitor the emergence and changes in the  
17               patterns of antimicrobial resistant pathogens in indi-  
18               viduals;

19               (2) study the molecular epidemiology of such  
20               pathogens;

21               (3) evaluate the efficacy of new and existing  
22               interventions to prevent or limit the emergence of  
23               antimicrobial resistance throughout the geographic  
24               region of the site;

1           (4) provide to the Centers for Disease Control  
2           and Prevention isolates of resistant pathogens, and  
3           in particular, pathogens that show new or atypical  
4           patterns of resistance adversely affecting public  
5           health;

6           (5) conduct clinical research to develop natural  
7           histories of infectious disease and to study duration  
8           of antimicrobial use related to resistance develop-  
9           ment, among other things;

10          (6) assess the feasibility, cost-effectiveness, and  
11          appropriateness of surveillance and screening pro-  
12          grams in differing health care and institutional set-  
13          tings, such as schools; and

14          (7) evaluate current treatment protocols and  
15          make appropriate recommendations on best practices  
16          for treating drug resistant infections.

17          (e) COORDINATION.—The sites established under  
18          subsection (a) shall share data and cooperate with the  
19          Centers for Disease Control and Prevention and the Na-  
20          tional Institutes of Health.

21          (f) DATA ACCESS.—The Director of the Centers for  
22          Disease Control and Prevention and the Director of the  
23          National Institutes of Health shall ensure that summary  
24          reports of data obtained by the Antimicrobial Resistance  
25          Surveillance and Research Network sites are made avail-

1 able to the Antimicrobial Resistance Task Force and, in  
 2 a manner consistent with section 8 of this Act, with the  
 3 Public Health Antimicrobial Advisory Board and the pub-  
 4 lic, for review on an ongoing basis .

5 **SEC. 6. SUPPLEMENT NOT SUPPLANT.**

6 Section 319E(f) of the Public Health Service Act (42  
 7 U.S.C. 247d–5(f)) is amended to read as follows:

8 “(f) SUPPLEMENT NOT SUPPLANT.—Funds appro-  
 9 priated under this section shall be used to supplement and  
 10 not supplant other Federal, State, and local public funds  
 11 provided for activities under this section, including funds  
 12 appropriated for the Centers for Disease Control and Pre-  
 13 vention and the National Institutes of Health.”.

14 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

15 Section 319E(g) of the Public Health Service Act (42  
 16 U.S.C. 247d–5(g)) is amended to read as follows:

17 “(g) AUTHORIZATION OF APPROPRIATIONS.—

18 “(1) AUTHORIZATION.—There are authorized to  
 19 be appropriated to carry out this section (other than  
 20 subsection (b)) \$45,000,000 for fiscal year 2010,  
 21 \$65,000,000 for fiscal year 2011, and \$120,000,000  
 22 for fiscal years 2012 through 2014.

23 “(2) ALLOCATION.—Of the amount appro-  
 24 priated to carry out this section for a fiscal year, not  
 25 less than one-third of such amount shall be made

1       available for activities of the Centers for Disease  
2       Control and Prevention under subsections (a)(3)(B)  
3       and (c), of which an appropriate amount shall be al-  
4       located to educational programs under subsection (c)  
5       dedicated to the reduction of inappropriate anti-  
6       microbial use.”.

7   **SEC. 8. PROTECTION OF CONFIDENTIAL AND NATIONAL SE-**  
8                   **CURITY INFORMATION.**

9       Except as otherwise required by law, this Act (and  
10      the amendments made by this Act) shall not permit public  
11      disclosure of trade secrets, confidential commercial infor-  
12      mation, or material inconsistent with national security  
13      that is obtained by any person under this Act.

○